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TECH CENTER 1600/2901

In re Patent Application of

GLENN et al.

Appln. No. 09/266,803

Filed: March 12, 1999

FOR: ADP-RIBOSYLATING EXOTOXIN USED FOR TRANSCUTANEOUS
IMMUNIZATION



Atty. Ref.: 4057-8

Group Art Unit: 1644

Examiner: G. Ewoldt

#21/B

gms

1/9/02

(T.E.)

* * *

AMENDMENT UNDER 37 CFR § 1.116

December 31, 2001

Hon. Commissioner for Patents
Box AF
Washington, D.C. 20231

Sir:

In reply to the pending Office Action (Paper No. 18) of August 14, 2001, entry and consideration of the following amendments and remarks are respectfully requested.

IN THE SPECIFICATION

Kindly enter the following amended paragraphs.

Do not
Enter
BSE
1/26/02
B1
Page 25, delete the fourth paragraph starting on line 20 and replace it with the following:

Alving et al. (1986) injected liposomes comprising lipid A as an adjuvant for inducing an immune response to cholera toxin (CT) in rabbits and to a synthetic protein consisting of a malaria oligopeptide containing four tetra-peptides (Asn-Ala-Asn-Pro, SEQ ID NO:1) conjugated to BSA. The authors found that the immune response to cholera toxin or to the synthetic malaria protein was markedly enhanced by encapsulating the antigen within the liposomes containing lipid A, compared to similar liposomes lacking lipid A. Several antigens derived either from the circumsporozoite protein (CSP) or from merozoite surface proteins of *Plasmodium falciparum* have been encapsulated in liposomes containing lipid A. All of the malaria antigens that have been encapsulated

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01 FC:103 432.00 CH
02 FC:102 84.00 CH

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Appln. No. 09/266,803

Filed: March 12, 1999

Title: ADP-RIBOSYLATING EXOTOXIN USE FOR TRANSCUTANEOUS IMMUNIZATION

Assistant Commissioner for Patents
Washington, DC 20231

Atty Dkt. 4057-8

C#/M#

Group Art Unit: 1644

Examiner: G. Ewoldt

Date: December 31, 2001

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TECH CENTER 1600/2900

**RESPONSE UNDER RULE 116
EXPEDITED HANDLING PROCEDURES**

Sir:

AMENDMENT UNDER 37 CFR § 1.116

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

Fees are attached as calculated below:

| | | | | |
|--|----|----------------------|----|------------|
| Total effective claims after amendment | 64 | minus highest number | | |
| Previously paid for | 40 | (at least 20) = | 24 | x \$ 18.00 |
| | | | | \$ 432.00 |

| | | | | |
|------------------------------------|---|----------------------|---|------------|
| Independent claims after amendment | 6 | minus highest number | | |
| Previously paid for | 5 | (at least 3) = | 1 | x \$ 84.00 |
| | | | | \$ 84.00 |

| | |
|--|---------|
| If proper multiple dependent claims now added for first time, add \$280.00 (ignore improper) | \$ 0.00 |
|--|---------|

| | |
|--|-----------|
| Petition is hereby made to extend the current due date so as to cover the filing date of this Paper and attachment(s) (\$110.00/1 month; \$400.00/2 months; \$920.00/3 months) | \$ 400.00 |
|--|-----------|

| | |
|---|-----------|
| Terminal disclaimer enclosed, add \$ 110.00 | \$ 110.00 |
|---|-----------|

| | |
|---|---------|
| <input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$740.00) | \$ 0.00 |
| <input type="checkbox"/> Please enter the previously unentered, filed | |
| <input type="checkbox"/> Submission attached | |

SUBTOTAL \$ 1026.00

| | |
|---|----------|
| If "small entity," then enter half (1/2) of subtotal and subtract | -\$ 0.00 |
|---|----------|

| | |
|--|---|
| <input type="checkbox"/> Applicant claims "small entity" status. | <input type="checkbox"/> Statement filed herewith |
|--|---|

| | |
|--|---------|
| Rule 56 Information Disclosure Statement Filing Fee (\$180.00) | \$ 0.00 |
|--|---------|

| | |
|------------------------------------|---------|
| Assignment Recording Fee (\$40.00) | \$ 0.00 |
|------------------------------------|---------|

| | |
|--|------|
| Other: SEQUENCE LISTING AND FLOPPY DISK IN COMPUTER READABLE FORM | 0.00 |
|--|------|

TOTAL FEE CHARGED TO DEPOSIT ACCOUNT \$ 1026.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYTE P.C.

By Atty.: Gary R. Tanigawa, Reg. No. 43,180

Signature: Gary Tanigawa